

REMARKS

Status of the Claims.

Claims 1, 6-19, 23, and 45-69 are pending with entry of this amendment, no claims being cancelled and no claims being added herein. Claim 69 is amended herein. This amendment introduces no new matter. Support is found, for example, at page 26, lines 10-12.

Objections to the specification.

The Examiner objected to the specification because the priority claim allegedly required insertion of the issued patent numbers and clarification of the relationship of the 08/546,130 application. The priority claim is amended herein thereby obviating this objection.

The Examiner objected to the specification because of the reference to "(e.g.@@)" on page 29, line 29. The paragraph at page 29, line 29 is amended herein obviating this objection.

35 U.S.C. §112, First Paragraph.

Claim 69 was rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to meet the description requirement. In particular, the Examiner alleged that claim 69 comprises all hapt5ens and antigenic molecules without the qualification that the labeled antisera or monoclonal antibodies be available.

While Applicants do not agree with the Examiner's position, to expedite prosecution, claim 69 is amended to recite:

69. The isolated nucleic acid of claim 1, wherein the labeled polynucleotide sequence comprises a biotin moiety, a dioxigenin moiety, **a hapten for labeled antisera or a monoclonal antibody, or an antigenic protein for labeled antisera or a monoclonal antibody.** [emphasis added]

In view of this amendment, Applicants believe claim 69 meets the description requirement and the rejection under 35 U.S.C. §112, first paragraph, should be withdrawn.

35 U.S.C. §102.

A) Tanner *et al.*

Claims 1, 6, 8, 10, 12, 14, 16, 18, 45, 46, 47-61, 63, 64, 68, and 69 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Tanner *et al.* (1994) *Cancer Res.* 54: 4257-4260. In particular, the Examiner alleges that the specification teaches that the specification states that SEQ ID NO:1-10 and 12 are nucleic acid sequences within the 20q13 amplicon and thus would be comprised within the cosmid (RMC20C001). Applicants traverse.

Contrary to the Examiner's assertion, SEQ ID NOs 2-9 (recited in independent claim 1) **are not** within the RMC20C001 cosmid and consequently not anticipated by Tanner *et al.* AT page 16, lines 18-21, the specification expressly states:

The minimum common region of amplification was mapped to a ≈600 kb interval flanked by P1 clones #3 and #12 with the highest level of amplification detected by P1 **clone #38 corresponding to RMC20C001** (Figure 4).

Figures 3 and 4 show the location of the various P1 clones. Inspection of Table 3, at page 21, shows that SEQ ID NO:2 (1b11) corresponds to map number 2, SEQ ID NO:3 (cc49) corresponds to map number 9, SEQ ID NO:4 (cc43) corresponds to map number 10, SEQ ID NO:5 corresponds to map number 13, SEQ ID NO:8 corresponds to map number 1, and so forth. Inspection of Figures 3 and 4 show that none of these P1 clones overlap P1 clone #38 (RMC20C001).

With respect to SEQ ID NO:9 (ZabC1), inspection of Figure 3 shows that RMC20C001 (P1 clone 38) is localized near locus D20S183. In contrast, inspection of Figure 7 in related application 08/892,695 shows that ZABC1 is localized near locus D20S211. It can be seen in Figure 3 that D20S211 is quite some distance from D20S183 and there is clearly no overlap between RMC20C001 and ZABC1.

The Examiner is further reminded that inspection of Figures 3 and 4 will clearly establish that the RMC20C001 cosmid **does not** span the entire amplicon. Moreover, with respect to SEQ ID NOs: 6 (GCAP) and 7 (1b4), the Examiner has simply failed to establish that RMC20C001 overlaps these sequences. In view of the foregoing, the Examiner has failed to make her *prima facie*

case and the rejection of claim , 8, 10, 12, 14, 16, 18, 45, 46, 47-61, 63, 64, 68, and 69 in light of Tanner *et al.* should be withdrawn.

B) New England Biolabs Catalog.

Claims 58-61 were rejected under 35 U.S.C. §102(b) as allegedly anticipate by the New England Biolabs Catalog (1993-1994, page 91) allegedly provided in a previous Office Action. Applicants note that paper 27 (mailed 9/13/99) shows pages 152-153 of the New England Biolabs catalogue being cited, not a citation of page 91.

Nevertheless, Applicants note that the Examiner has offered no objective evidence for her assertion that the **random primers** allegedly disclosed in this application would specifically hybridize to SEQ ID NOs: 2, 3, or 12 under stringent conditions that "comprise a 0.02 molar salt concentration and a temperature of at least 60°C" as recited in independent claim 58. No sequence alignments are provided. No calculations of hybridization efficiency are presented. Indeed the Examiner has offered no objective evidence to support her assertion. Absent any evidence whatsoever establishing that the primers allegedly disclosed in the New England Biolabs catalogue hybridize to the recited sequences under the claimed conditions, the Examiner has simply failed to make her *prima facie* case. Accordingly, the rejection of claims on these grounds should be withdrawn.

Obviousness-type double patenting.

Claims 1, 6-19, 23, and 45-67 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 11-17 of U.S. Patent 5,801,021. Claims 1, 6-13, 23, 45-53, 58-60, and 63 were rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-9 of U.S. Patent 5,892,010.

Upon an indication of otherwise allowable subject matter, Applicants will provide a Terminal Disclaimer.

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for an indication of allowable subject matter. Should the Examiner seek to maintain the rejections, Applicants request a telephone interview with the Examiner and the Examiner's supervisor.

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If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 769-3513.

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Respectfully submitted,



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